1614

Express Mailing Label No.: EV 312715498 US

Qate of Deposit: December 12, 2003

Attorney Docket No. 22058-544

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS:

Warne, et al.

SERIAL NUMBER:

DEC 1 2 2003

10/663,264

EXAMINER:

Not Yet Assigned

FILING DATE:

September 16, 2003

ART UNIT:

1614

For:

DELAYED RELEASE FORMULATIONS FOR ORAL

ADMINISTRATION OF A POLYPEPTIDE THERAPEUTIC AGENT

AND METHODS OF USING SAME

**Mail Stop IDS** 

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## TRANSMITTAL LETTER

Transmitted herewith for filing in the present application are the following documents:

- 1. Information Disclosure Statement (1 page), in duplicate;
- 2. Modified Form 1449/PTO (1 page), in duplicate;
- 3. Copies of Cited References A1-11; B1; C1; and
- 4. Return Postcard.

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 542-6000, Boston, Massachusetts.

The Commissioner is authorized to charge any fees that may be due, or to credit any overpayment, to the undersigned's account, Deposit Account No. 50-0311 Ref. No. 22058-544. A duplicate copy of this transmittal letter is enclosed herewith.

Respectfully submitted

David E. Johnson Reg. No. 4,80

Attorney for Applicants

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Date: December 12, 2003

TRA 1861524v1

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## INFORMATION DISCLOSURE STATEMENT

Applicants make of record the documents listed on the attached modified Form PTO-1449 (submitted in duplicate) in the above-identified application, copies of which are enclosed.

This Information Disclosure Statement is being submitted within three months of filing the application. Accordingly, no fee or certification is believed required. However, please charge any fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311 Reference No. 22058-544.

Respectfully submitted

David Johnson, Reg. No. 41 Attorney for Applicarts

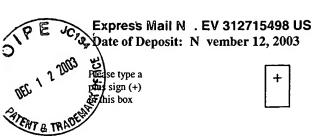
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Date: December 12, 2003

TRA 1861520v1



PTO/SB (12-97)

Approved for use through 9/30/00. OMB 0651-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Modified Form 1449/PTO  INFORMATION DISCLOSURE  STATEMENT BY APPLICANT						Application Number	10/663,264				
						Filing Date	September 16, 2003				
						First Named Inventor		Warne			
						Group Art Unit	1614				
						Examiner Name Not Yet Assigned			3		
	(use	as many	sheets as n	ecessary)		Attorney Docket Numl	ber	22058-544			
						. PATENT DOCUMENTS					
Exam Initials	Cite No.			Issue Date	Name of Patentee(s) or Applicant(s)		nt(s) 	Class	Sub Class	Filing If App	Date ropriate
	A1	5,215,895		06/0193	Bennett, et al.		435	69.52			
	A2	5,270,181		12/14/93	McCoy, et al.		435	69.7			
	A3	5,292,646		03/08/94	McCoy, et al.		435	69.7			
	A4	5,679,339		10/21/97	Keith, et al.		424	85.2			
	A5	6,077,541		06/20/00	Chen, et al.		424	480			
	A6	6,126,933		10/03/00	Warne, et al.		424	85.2			
	A7	6,174,548 B1		01/16/01	Chen, et al.		424	474			
	A8	6,207,682 B1		03/27/01	Andersen, et al.		514	317			
	A9	6,331,316 B1		12/18/01	Ullah, et al.		424	482			
	A10	6,428,810 B1		08/06/02	Bergstrand, et al.		424	480			
	A11	6,540,993 B1		04/01/03	Warne, et al.		424	85.2			
				U.S. F	PUBLIS	HED APPLICATION DOC	UMENTS				
Exam Initials	Cite No.			Published Date	Name of Patentee(s) or Applicant(s)		Class	Sub Class	Filing Date If Appropriate		
				*	FOREI	GN PATENT DOCUMENT	S				
Exam Initials	Cite No.				Name of Patentee(s) or Applicant(s)		Date of Publication		Translation Yes No		
	B1	wo	91/0749	)5	GENETICS INSTITUTE, INC.			05/30/91		Yes	
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Exam Initials	Cite No.	Name	of Author	r, Title (when a	ppropri	ate), Publication, Volume,	Page(s), Date	, Etc.			
mitials	C1										
	•	Lymphopoietic and Hematopoietic Cytokine", <i>Proc. Natl. Acad. Sci. USA</i> , 87:7512-7516 (1990).									
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered.

Include copy of this form with next communication to applicant.